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No. 03-1237

IN THE SUPREME COURT OF THE UNITED STATES

MERCK KGaA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE and TELIOS PHARMACEUTICALS, INC.,

Respondents.

On Writ of Certiorari To The United States Court of Appeals For the Federal Circuit

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONER

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BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONER

I. INTEREST OF *AMICUS CURIAE*[1/]

AARP is a nonpartisan, nonprofit membership organization of more than 35 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. AARP works to foster the health and economic security of individuals as they age, including attempting to ensure access to quality and economical health care.

1/ No counsel for any party authored any portion of this brief. No persons other than *amicus curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

Access to prescription drug treatments is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over 65, although only 13% of the population, account for 34% of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs.[2/] Spending on prescription drugs has skyrocketed over the last decade. In 1990, total national health expenditure on prescription drugs was $40.3 billion, by 2000 it was $121.5 billion. For 2003, it was $179.2 billion.[3/] The rising price of prescription drugs has left many older Americans unable to afford necessary medications. Therefore, AARP supports efforts at the state and national levels to increase access to more affordable drugs.

In this case, AARP believes the Federal Circuit incorrectly interpreted the scope of the statutory exemption to patent infringement which Congress enacted in the Drug Price Competition and Patent Term Restoration Act of 1984 § 202, 35 U.S.C. § 271(e)(1) (2005). *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) narrows the exemption to such a degree that it will hamper advances in medical technology and further drive up the costs of drug development. Both of these consequences harm older Americans. In light of the significance of the issues presented by this case, AARP respectfully submits this brief *amicus curiae* urging the Court to overrule the decision of the Federal Circuit.

II. SUMMARY OF ARGUMENT

The Federal Circuit's decision that basic biomedical and

2/ Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000) *available at* http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726.

3/ Centers for Medicare and Medicaid Services, *National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Select Calender Years 1980-2003,* at http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp.

preclinical drug research to develop information required for drug approval is not exempt from patent infringement contradicts the language of 35 U.S.C. § 271(e)(1) and conflicts with congressional intent. The mistaken decision in *Integra* was based on a faulty analysis which focused only on what the Food and Drug Administration (FDA) requires for generic drug approval rather than the information which necessarily must be developed for regulatory approval of innovative drugs. Because the exemption is not limited to the the generic drug approval process, the Court of Appeals erred when it excluded the preclinical research done in this case from the scope of the exemption. The Federal Circuit's unwillingness to allow a broader experimental use exemption to patent infringement as Congress intended will lead to delay of medical advances by hampering the free exchange of scientific knowledge and by postponing competition beyond the patent term. The costs for prescription drugs, which already are so high as to prohibit many people from accessing their benefits, will be driven even higher. This Court should reverse the Federal Circuit, and hold that research using a patented invention with the objective of obtaining regulatory approval for pharmaceuticals is exempt from patent infringement.

III. ARGUMENT

A. The Federal Circuit's Decision Denying Pre-clinical Drug Research Exemption From Patent Infringement Improperly Limits the Protection Congress Gave Researchers Seeking to Develop New Drugs.

The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments) included a patent infringement exemption to allow for the use of a patented invention to develop information necessary to obtain regulatory approval for drugs. The statute provides that:

> it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of

> information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). The statutory language that using a patented invention "solely for uses reasonably related to the development and submission of information" under a federal law regulating drugs is both plain and broad. The Federal Circuit determined that the use of the words "solely" and "reasonably related" meant there was some limitation to the scope of the exemption, a logical reading of these words of limitation. But in its attempt to define the outer boundaries of the exemption, it failed to appreciate the breadth of the heart of the exemption.

The strong presumption that the plain language of a statute expresses congressional intent is rebutted only in "rare and exceptional circumstances" in which a contrary legislative intent is expressed. *Ardestani v. I.N.S.*, 502 U.S. 129, 134 (1991). However, in the case of this statute, there can be no doubt of congressional intent to create a broad exemption to permit the use of patented products in experiments with the aim of identifying a potential drug product – even where an application for approval to the FDA is ultimately not made. *See* H.R. Rep. No. 98-857, at 45 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678. "A party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application approval would be sought." *Id.*

As this Court has recognized, the statutory scheme of Hatch-Waxman intended to preserve patent holders' rights compromised by the time it took to secure regulatory approval, and, at the same time, prevent a *de facto* patent extension equal to the time it would take a competitor to prepare to comply with the regulatory requirements to bring a drug or medical device to market. *See*, *Eli Lilly v. Medtronic*, 496 U.S. 661, 669 (1990) (noting the Act was "designed to respond to two unintended distortions of the . . . patent term produced by the requirement that certain products must receive premarket

regulatory approval.") The decision in *Medtronic* broadly construed 35 U.S.C. § 271(e)(1), applying it both to medical device manufacturers as well as drug manufacturers, to allow "competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Medtronic*, 496 U.S. at 671.

The Federal Circuit's understanding of what is "necessary to obtain regulatory approval" is too restricted. It prohibits "general biomedical experimentation" from falling within the safe harbor even though the statute itself does not contain any such limitation. *Integra*, 331 F.3d at 868. Rather than focusing on the clear and broad language of the statute – which allows the use of a patented invention as long as it is "reasonably related to the development and submission of information" to the FDA, the court's analysis went astray because it focused too heavily on the legislation's goals with respect to generic drug development. In order to determine what is reasonably related to the development of information required to be submitted the FDA for an innovator drug, as this case requires, it is a mistake to solely examine what is required for approval of a generic drug. Admittedly, Hatch-Waxman largely dealt with the approval of generic drugs, but Congress did not limit the reach of the safe harbor to the development of information for the generic drug approval process. Congress could have easily made the subsection read "a Federal law which regulates the manufacture, use or sale of *generic* drugs," but it did not. The Federal Circuit acknowledged that § 271(e) was not limited to generic drug approval, but it nonetheless used the generic application process as its prototype in order to analyze what kind of information the FDA examines, and thus, what activity done to gather that information would not be considered an act of patent infringement. The court's singular fixation on generic drugs can be seen as it concludes:

> The meaning of the phrase "reasonably related to the development and submission of information" as set forth in § 271(e)(1) is clearer in the context of the role of the 1984 Act in facilitating expedited approval of a generic version of a drug previously approved by the FDA. . . . The exemption viewed in this context does not endorse an

> interpretation of § 271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market. It does not, for instance, expand the phrase "reasonably related" to embrace all stages of the development of new drugs merely because those new products will also need FDA approval. Thus, § 271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process. The safe harbor does not reach any exploratory research that may rationally form only a predicate for future FDA clinical tests.

Integra, 331 F.3d at 866-867.[4/]

It must be recognized that the FDA's approval process for generic drugs is markedly different from the FDA's approval process for a new drug. The entire process of approving a generic is considered an "abbreviated new drug application" precisely because the FDA's process for approving a generic dispenses with requiring the underlying scientific testing that would be required of a pioneer drug. Therefore, when examining the activity necessary for the process of applying for approval for a new drug, a court should allow for the fact that contrary to the generic application process, the FDA necessarily requires all innovator drug applicants to develop "exploratory" biomedical research before clinical trials can begin. In its brief on petition for a writ of *certiorari* in this case, the Solicitor General illustrated that the FDA requires the development and submission of pre-clinical research when it evaluates a proposed new drug through the Investigational New Drug

4/ This parsimonious reading is rather surprising given that the Federal Circuit acknowledged this exemption was created to overrule its prior decision, *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* 733 F.2d 858 (Fed. Cir. 1984), which had held that experimental use of a drug during pre-marketing FDA approval activities were infringements. *Integra* 331 F.3d at 865. *See also* H.R. Rep. No. 98-857, 27, 71 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2467, 2681, 2711. *Roche* was a generic drug case, and did not deal with pioneer research.

(IND) process. Brief for the United States as *Amicus Curiae*, at 9-11. Regardless of how scientific testing is characterized, whether as "clinical" or "pre-clinical" or "exploratory," biomedical research, under the language of § 271(e)(1), if done "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs," falls within the exception.

The Federal Circuit's refusal to apply the § 271(e)(1) exemption to preclinical research which forms a predicate for FDA approval not only provides far more patent protection than a literal reading of the statute suggests, but it also frustrates the intent of Congress to allow pharmaceutical researchers to conduct experimentation in order to prepare to compete without risking patent liabilities. The aim of the research in this case was to develop the information which is a prerequisite for obtaining drug approval. That is, identifying a product which could be a useful drug which then could be submitted to the FDA for approval for further development and clinical trials. Without doing the pre-clinical research to identify a candidate for the clinical testing required by federal law no entity would be able to submit an application for approval.[5/] Under the Federal Circuit's limited reading of the exemption, all further testing and development by scientists interested in medical advancement based upon an older, patented technology would have to wait until patent expiration before beginning. This delay would create an effective extension of the patent term because the experimentation necessary to create a new product would have to wait until scientists could freely use the product. Hatch-Waxman sought to eliminate this kind of extension; the legislative history stated that only the extensions provided for in the Act should be permitted. *See* H.R. Rep. No. 98-857, at 46 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679. ("There should be no other direct or indirect method of extending patent term.") Because the Federal Circuit's interpretation of

5/ The federal requirements for drug approval are set forth in the Federal Food, Drug, and Cosmetic Act of 1938 (as amended), 21 U.S.C. § 301 *et seq.* (2005) and its implementing regulations, 21 C.F.R. § 314 *et seq.* (2005).

"reasonably related to the development" contradicts the plain language of the statute and is inconsistent with Congressional intent, it should be overruled.

B. Too Much Protection for Patent Rights Stifles Innovation and Increases Costs Resulting in Reduced Access to Pharmaceuticals

The practical effect of the Hatch Waxman Amendments and other laws since the 1980's[6/], as well as ongoing judicial interpretation of patent law, has been to greatly extend intellectual property protection afforded to prescription drugs.

> Over the past two decades, Congress has enacted a series of laws that have greatly increased the "effective patent life" enjoyed by brand name prescription drugs . . . . Considered individually, each of these laws offers a reasonable approach to stimulate pharmaceutical innovation and ensure broad access to new medications. Viewed collectively, the laws have conferred multiple and additive protection on prescription drugs.

Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, NIHCM Issue Brief at 1 (2000), *available at* http://www.nihcm.org/prescription.pdf. The "average effective patent life of many new drugs has increased by at least 50 percent between the early 1980s and today." *Id.* During that

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6/ *See, e.g.*, Patent Term Guarantee Authority Act, 35 U.S.C. § 154(b) (1999) (requiring the federal Patent and Trademark Office to compensate for delays in patent processing of over three years); Uruguay Round Agreements Act, 19 U.S.C. §§ 3501-3624 (1994) (changing the terms of all patents in the U.S. from 17 years from to the date of issue to 20 years from the date of application and allowing the longer of the two terms for some drugs already on the market); The Orphan Drug Act, 21 U.S.C. §§ 360aa-ee (1983) (providing seven years of market exclusivity to drugs for rare diseases, and creating tax credits for 50% of the cost of researching and developing those drugs).

same period, patents on biotechnological products began to be expansively granted and the courts have exhibited a willingness to support an ever wider tolerance to affirm patent validity for what can be called "nonnaturally occurring" living things such as genetically modified organisms and purified or modified natural proteins. John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 Emory L.J. 101, 123-130 (2001)(hereinafter Golden).

Even before the Federal Circuit's decision in *Integra*, commentators noted their concerns about the over-extension of American patent law which resulted in impeding biotechnological development. *See* Golden, at 175-177 (discussing "danger that patents will impede both privately and publicly funded research, by making it impossible, or at least more costly, for researchers to obtain the tools and materials needed for free scientific inquiry.") *See also*, *Gene Patents and Other Genomic Inventions:* Hearing Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary, 106th Cong. 79 (2000)(statement of Jon F. Merz, on July 13, 2000), *available at* http://judiciary.house.gov/legacy/merz0713.htm,
(survey of laboratory physicians showed that 25% had abandoned development of a clinical test, and 48% did not develop a clinical test because of patents).

Following the decision, those concerns have ripened into alarm. *See* Rochelle Dreyfuss, *Symposium: Biotechnology Patents Get Special Treatment: Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457, 472 (Fall 2004) ("it is time to put some serious thought into protecting the vitality of the public domain of science"); Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 Baylor L. Rev. 917, 922 (2004) (in light of judicial refusal to apply an experimental use defense, calling for Congressional action and raising specter of flight of intellectual capital as drug research moves off shore to countries like Germany, Japan and the United

Kingdom which all expressly provide for broad experimental use exception to patent infringement); Nicholas Groombridge and Sheryl Calabro, *Integra LifeSciences v. Merck – Good for Research or Just Good For Research Tool Patent Owners?*, 22 Biotechnology L. Rep. 462, 471 (2003) (concluding that the decision will serve as a "disincentive to further progress in the treatment and prevention of disease.")

In her dissent in this case, Judge Newman recognized the problem of over protection of patents causing delay in scientific achievement, stating that if research was "subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology." *Integra*, 331 F.3d at 875.

Experimentation using a patented invention is theoretically possible through licensing, but it is not always practically available. In a pilot survey of institutions holding patents on human nucleic acid sequences, "nearly three quarters of all respondents . . . said that they had at least one [licensing] negotiation breakdown without agreement in the past year." Michelle R. Henry, *et al.*, *A Pilot Survey on the Licensing of DNA Inventions*, 31 J.L. Med. & Ethics 442, 446 (2003).

Assuming a license can be obtained at all, researchers would have to pay fees to the patent holder to use the product in their experiments in order to develop information necessary to apply for FDA approval of a drug. Whatever the cost, it will certainly add to the expense of developing a new drug, as well as add to the time it takes to develop the drug while the licensing negotiation takes place.[7/] We can be assured that these costs

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7/ The amount it costs to develop a new drug is the subject of intense debate. A 2001 Tufts Center Study claims it costs $802 million, while Public Citizen argues that the true figure is likely to be about $200 million. *Compare* Tufts Center for the Study of Drug Development, *Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million* (Nov. 30, 2001), *available at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 *with* Public Citizen, *New Study Expected to Significantly Overstate Drug Industry R&D Costs* (Nov. 28, 2001), *available at* http://www.publiccitizen.org/pressroom/release.cfm?ID=942.

will ultimately be borne by the consumers who suffer not only because medical advances are delayed, but because as the price of prescriptions rise, fewer people can afford the treatments.

It is no coincidence that along with the increase in patent protection, prescription drug expenditures have also increased.[8/] Prescription drug spending is one of the fastest growing components of health care expenditures, increasing at double digit rates for each of the last eight years ending in 2004.[9/] Spending for prescription drugs was projected to grow by 12.9% from 2003 to 2004, outpacing growth in all other health services.[10/] U.S. outpatient prescription drug expenditures were 9.7% of national health expenditures in 2002 and are projected to rise to 15.5% of national health care expenditures by the year 2013.[11/] Increased demand by an aging population,

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8/ The increase in drug prices can not be attributed to inflation. The gap between rising prescription drug prices and the general rate of inflation is in fact widening over time. On average, the manufacturer prices for 193 widely used brand name prescription drugs rose at an annual rate of 4.1% in 2000, but accelerated to 6.9% in 2003; the annual rate of general inflation fell from 3.4% in 2000 to 2.3% in 2003. David Gross, Stephen Schondelmeyer, Susan Raetzman, *Trends in Manufacturers Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 through 2003*, at 5 (AARP Public Policy Institute 2004), *available at* http://research.aarp.org/health/2004_06_drugprices.pdf.

9/ Kaiser Family Foundation, *Prescription Drug Trends (Fact Sheet)* at 1 (October 2004), *available at* www.kff.org/rxdrugs/3057-03-index.cfm.

10/ Stephen Heffler, *et al.*, *Trends: Health Spending Projections Through 2013*, W4 Health Affairs 79, 81 (2004), http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.79v1.pdf.

11/ *Id.*

http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 *with* Public Citizen, *New Study Expected to Significantly Overstate Drug Industry R&D Costs* (Nov. 28, 2001), *available at* http://www.publiccitizen.org/pressroom/release.cfm?ID=942. as well as new, more expensive drug therapies becoming available, have contributed to rising drug spending. However, increased drug prices are a substantial contributor to the increase in our nation's expenditures on drugs. The increase in prices is estimated to constitute a quarter to one-third of the rise in drug spending.[12/]

Studies show that people respond to rising drugs costs by not purchasing necessary drugs or engaging in potentially unsafe drug administration practices, such as pill spitting or hoarding when they can not afford the medications. Susanna Smith, *Health in the Public Interest: Cost-effective Prescribing* (Amer. Med. Assn. 2004), *available at* http://www.ama-assn.org/ama/pub/category/print/9150.html#3. Doctors report that the primary reason for patient non-compliance with medication regimes is a patient's inability to pay for prescription drugs. *Id.* A study analyzing the relationship between cost and purchases from a national sample of people 65 and older found that, "[a] one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year." Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000). There is "specific, empirical evidence that financial barriers compel older Americans to forgo needed drug treatment." *Id.* A national survey of Americans aged 45 or older reported that more than one in five (22%) did not fill at least one prescription prescribed by their doctor. The cost of the drug was the main reason people cited for not getting their

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12/ *See, e.g.*, David Kreling et al., *Prescription Drug Chartbook: An Update*, at 40 (Kaiser Family Foundation 2001) available at http://www.kff.org/rxdrugs/upload/13796_1.pdf; Stanley S. Wallack et al., *Recent Trends in Prescription Drug Spending for Insured Individuals Under 65 and Age 65 and Older* (Schneider Institute for Health Policy, Brandeis Univ., 2001).

prescription filled.[13/] Of particular concern is the fact that cost deters a growing proportion of the population from taking medically necessary medicines, up from 13% during a 1986 survey to 22% in 2002.[14/]

Driving up the prices consumers pay for medicine thereby decreasing access is bad public policy, particularly when favoring patent protection under the circumstances of this case is counter-productive to the public interest.

> [A]t a time when patents threaten to lay claim to segments of the life sciences' core subject matter, patent law must devise a way to police the public property line . . . At some point, an expansive reading of patent law produces more harm than gain, creating transactions costs and other allocational in-efficiencies that interfere with publicly funded science and do not provide sufficient countervailing incentives for research. Patent law may have reached this point already with regard to the patenting of genetic sequences.

Golden, at 190-191.

CONCLUSION

"The right to conduct research to achieve [further technologic advances] need not, and should not, await expiration of the patent." *Integra*, 331 F.3d at 873 (J. Newman dissenting). Where Congress has already indicated that activity using a patented invention to develop information needed to obtain regulatory approval of drugs is not patent infringement, the courts must apply the law to protect research for future medical advancement.

13/ AARP, *Prescription Drug Use Among Persons Age 45+: A Chart Book June 2002* at 24-25 (2002) *available at* http://research.aarp.org/il/rx_charts.pdf.

14/ *Id.* at 72.

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